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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
|---|----------------|----------------------|-------------------------|-------------------------|--|
| 10/071,667 | 02/08/2002 | Kathy K. Wang | OSTEONICS 3.0-380 | 4016 | |
| 530 7 | 590 05/06/2004 | | EXAMINER | | |
| LERNER, DAVID, LITTENBERG, | | | PRIDDY, MICHAEL B | | |
| KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST | | | ART UNIT | PAPER NUMBER | |
| WESTFIELD, | NJ 07090 | | 3732 | 3732 | |
| | | | DATE MAILED: 05/06/2004 | DATE MAILED: 05/06/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|
| Office Action Summany | 10/071,667 | WANG ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Michael B Priddy | 3732 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period who Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 86(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | Responsive to communication(s) filed on | | | | | |
| 2a) This action is FINAL . 2b) ⊠ This | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-18,79 and 82-97</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-18,79 and 82-97</u> is/are rejected. | Claim(s) is/are objected to. | | | | | |
| | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| 11) The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action of form P10-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority documents application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applicati ity documents have been receive u (PCT Rule 17.2(a)). | on No ed in this National Stage | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 200308218. | 4) ☐ Interview Summary Paper No(s)/Mail Da | (PTO-413) | | | | |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-18 and 79 in Paper No. 20040223 is acknowledged. Applicant has also added new claims 82-97 that read on the elected invention and will therefore be examined with claims 1-18 and 79. An action on the merits of claims 1-18, 79 and 82-97 follows.

Claim Objections

Claim 89 is objected to because of the following informalities: in line 1, "wherein" should me –having--. Appropriate correction is required.

Claim 92 is objected to because of the following informalities: in line 2,
--directly-- should be inserted between "bonded" and "to". Appropriate correction is
required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wendt et al. (EP 98518 A2). Wendt et al. (as disclosed in the abstract) teaches a porous metal scaffold comprising a porous metal network having pores defined by metal webs ("porous, corrosion-proof, non-conductive partitions consisting of metal nets"), the webs covered with at least one layer of metal particles ("...coated with oxide ceramics, wherein the oxide ceramics layer contains metal particles"), the metal particles being bonded to the metal webs.

Claims 1-7, 11-13, 16-18 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowe, Jr. et al. Rowe, Jr. teaches a porous metal scaffold for use in an implantable medical device comprising: a porous metal network having pores defined by titanium webs 33, the webs 33 covered with at least one layer 35 of titanium particles, the titanium particles being bonded to the titanium webs 33; wherein said titanium webs 33 form a continuous inner skeleton of said porous metal scaffold; wherein the pore size may be varied by bonding additional layers of titanium particles to said at least one layer; wherein the pore size is varied by changing a size of the titanium particles; wherein the bonding is accomplished by sintering the titanium particles to said webs (lines 31-34 of column 3); wherein the metal scaffold is bonded directly to a solid metal substrate in the form of part of an orthopedic implant; and further comprising a biocompatible coating 37.

Claims 82-84, 86, 87, 91, 92, 93, 96 and 97are rejected under 35 U.S.C. 102(b) as being anticipated by Rowe, Jr. et al. (U.S. 4,542,539). Rowe, Jr. et al. teaches a porous metal scaffold for use in an implantable medical device comprising: a porous

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metal network having pores defined by titanium webs 33/35 formed on a tissue contacting surface 31 of the medical device, the titanium webs 33/35 being thicker on a side thereof 35 facing towards the tissue contacting surface, the webs 33/35 covered with at least a first layer of titanium particles 37, the titanium particles 37 being bonded to the titanium webs 33/35 to produce a final pore size; wherein the metal scaffold is bonded to a solid metal substrate 31; and wherein the bonding is accomplished by sintering the metal particles to said webs.

Concerning the limitations of claim 84, it is noted that the Examiner has interepreted layers 33 and 35 as one system of webs and layer 37 as titanium particles. In lines 8-9 of column 5 and lines 67-68, Rowe, Jr. et al. discloses the possibility of more than three layers. In such a situation, the fourth and subsequent layers could be considered "at least one additional layer of metal particles".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 14, 88 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe, Jr. et al. Rowe, Jr. et al. teaches all of the limitations of the present invention except the pore size ranges from 100 microns to 1000 microns with a plurality of pores having a size greater than about 100 microns. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to form the webs 33, 35 and 37 such that the pore size ranged from 100 microns to 1000 microns with a plurality of pores having a size greater than about 100 microns, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 9 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe, Jr. et al. Rowe, Jr. et al. teaches all of the limitations of the present invention except the pore volume ranges from 50% to 90%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the webs 33, 35 and 37 such that the pore volume ranged from 50% to 90%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 10 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe, Jr. et al. Rowe, Jr. et al. teaches all of the limitations of the present invention except the scaffold is formed into a shape having a thickness of .5 mm to 5 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct scaffold of Rowe, Jr. et al. to have a thickness of .5 mm to 5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 15 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe, Jr. et al. Rowe, Jr. et al. teaches all of the limitations of the present

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invention except the titanium particles have a size from 40 microns to 80 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct scaffold of Rowe, Jr. et al. using titanium particles of a size from 40 microns to 80 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael B. Priddy

May 4, 2004